Qualitative research to understand consumer opinions and preferences for emerging HIV prevention products among MSM in Atlanta, Houston, and Miami

Generic Information Collection Request under OMB #0920-1091

Section B: Supporting Statement

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EXHIBITS

1. Respondent Universe and Sampling Methods

Site Selection

We will conduct this study in three MSA's with high HIV incidence and prevalence: Atlanta, Georgia; Houston, Texas; and Miami, Florida.

Atlanta, GA. Atlanta is an area of high HIV incidence and prevalence accounting for almost 1 in every 4 HIV diagnoses in Georgia [1]. With 37,155 people living with HIV, metro Atlanta ranks fourth in the U.S. in HIV prevalence [2]; of this, 80% are males [3]. Among male HIV diagnoses, 69% involved male-to-male-sexual contact [3]. Black/African American MSM are disproportionately affected, with a HIV prevalence rate of 46% compared to the 13% prevalence rate among white MSM [4]. Kelley et al. found that MSM located in Atlanta reported 60% lower use of PrEP when compared to other major cities such as San Francisco [5]. These disparities show a need to understand the acceptability of emerging biomedical products among MSM in Atlanta.

Houston, TX. As of 2017, Houston is home to 25,831 people living with HIV, half of which are Black/African American, 24% of which are Hispanic/Latinx, and 28% percent of which are white[6]. Among men living with HIV in Houston in (76% of total), 64% reported male-to-male sexual contact as the transmission mode. In 2017, 1,133 people were newly diagnosed with HIV, 79% of whom were male. In 2018, data on PrEP use (from a single payer dataset of PrEP prescriptions) counted 9,442 PrEP users in Texas, whom 8,904 of whom are male, making Texas fourth in PrEP prescriptions (after NY, CA, and FL). [7] Zip code-level data (using the first 3 digits of the zip code) for 2016 estimates 957 PrEP users in Houston-area zip codes, of whom 899 are male.[8] AIDSVu estimates PrEP need by dividing the number of PrEP users by the number of people newly diagnosed with HIV in the previous year. For 2016, that ratio was 0.76 (957 PrEP users in 2016 and 1,260 new HIV diagnoses in Harris County in 2015), showing that more PrEP uptake is needed relative to the frequency of new HIV infections. By choosing Houston as a site, this study will examine an area with high need but with a sufficient number of PrEP users in the catchment area to recruit successfully.

Miami, FL. Miami, Florida had the highest new infection rate per capita of any U.S. city in 2016 [9]. Currently, there are 26,632 people living with HIV in Miami of which 74% are male [40]. The rate of black males living with an HIV diagnosis is 2.6 times that of white males [10]. 69% of HIV diagnoses were transmitted by male-to-male sexual contact [10]. One study found that only 41% of MSM in Miami had ever heard of PrEP and less than 2% actually reported taking the medication in the previous year [11]. This lack of knowledge presents an urgent need to focus efforts towards prevention and treatment strategies in the state of Florida particularly in Miami-Dade County.

Broward County, FL. South Florida is fully cognizant of the HIV/AIDS issue facing their state. Aside from Miami, Broward County was included on the list of top ten U.S. cities for rate of newly diagnosed HIV cases [12]. As of 2017, there were 20,661 Broward County residents living with HIV [13]. In the epidemiology report for Broward County, there were a total of 262 AIDS cases in 2017 resulting in a 66% decrease over the last 10 years [13]. According to the

data, adult male cases have increased 8% from 2008 to 2017 due to the increase in transmission among MSM [12]. Male-to-male sexual contact continues to be the main mode of exposure among adult males accounting for 78% of those cases [12].

Target Population

The total number of participants is n=120. There will be 60 participants taking part in the in-depth interviews (IDIs) and 60 participants taking part in the focus groups (FGs). There will be a total of 40 Black non-Hispanic MSM, 40 Hispanic/Latino MSM, and 40 White, non-Hispanic MSM

Exhibit 1.1 Summary of Recruitment Targets

Data Collection Activity	**Black, non-Hispanic**	**Hispanic/Latino**	**White, non-Hispanic**	**TOTAL**
FG aware of PrEP/not using	10 (2 FG, n = 5 men)	10 (2 FG, n = 5 men)	10 (2 FG, n = 5 men)	30
IDI aware of PrEP/not using	10	10	10	30
FG using PrEP	10 (2 FG, n = 5 men)	10 (2 FG, n = 5 men)	10 (2 FG, n = 5 men)	30
IDI using PrEP	10	10	10	30
TOTAL	**40**	**40**	**40**	**120**

	Atlanta	**Houston**	**Miami**	**TOTAL**
FG	20 (4 FG, n = 5 men)	20 (4 FG, n = 5 men)	20 (4 FG, n = 5 men)	60
IDI	20	20	20	60
TOTAL	**40**	**40**	**40**	**120**

Aware of PrEP, but not currently using:

Inclusion Criteria
- Male at birth
- Currently identifies as male
- 18 years or older
- Black/African American and White/non-Hispanic
- Hispanic/Latino and non-Hispanic/Latino
- Self-report of HIV negative/uninfected status
- Self-report report of condomless anal sex with one or more male partners in the last 6 months AND/OR report a sexually transmitted infection (STI) diagnosis within the last 6 months
- Reside in the Atlanta, Houston, or Miami MSAs
- Aware of PrEP, may or may not use PrEP (self-report of use)

Exclusion Criteria
- MSM who have never heard of PrEP
- Inability to provide consent for any reason
- Inability to speak and read English
- Currently participating in another HIV prevention study or program
- Staff member of an HIV prevention study or program

Currently on PrEP

Inclusion Criteria
- Male at birth
- Currently identifies as male
- 18 years or older
- Black/African American or White/non-Hispanic
- Hispanic/Latino and non-Hispanic/Latino
- Self-report of HIV negative/uninfected status
- Reside in the Atlanta, Houston, or Miami MSAs
- Aware of PrEP, may or may not use PrEP (self-report of use)

Exclusion Criteria
- Inability to provide consent for any reason
- Inability to speak and read English
- Currently participating in another HIV prevention study or program
- Staff member of an HIV prevention study or program

2. Procedures for the Collection of Information

Trained contract staff from the research team will carry out all information collection activities, not CDC staff. The partnering community-based organization staff as well as contract research staff will distribute recruitment materials (**Attachment 1**). These materials include a telephone number for interested parties to call for screening and scheduling purposes. Interested participants may be screened by phone. If eligible, the contract study team will work with each participant to find a convenient time and location to conduct the interview. Alternatively, interested participants may be recruited in-person, during which the contract research team would describe the study and screen the participant at the time of recruitment.

Prior to screening, interested staff, stakeholders, and clients will be told about the purpose of the study, informed how their information will be used, how their identity will be protected and how their information will be presented in a way that does not identify them, and of their right to withdraw from the study at any time without penalty. If they voluntarily agree to proceed, the research staff will conduct the screening in a private area, such as over the phone or in a place others cannot hear their answers. Client screening will last approximately 10 minutes and includes eligibility as well as demographic questions (**Attachments 2a**). Once the interested party is determined to be eligible, they will be invited to join the study. If they are not eligible or

choose not to participate, their screening information will be destroyed. If they agree to participate, contract study staff will collect the participants contact information (**Attachment 2b**) in order to schedule an interview.

After agreeing to participate, and prior to the interview or the focus group, informed consent will be covered. As part of the consent process, research staff will request permission to audio record the session in order to have an accurate record of the conversation. Participants must indicate their consent to the interview or focus group by signing the Informed Consent Form (**Attachments 3a and 3b**). Study staff will remind participants not to use full names or other identifying information during the session. After the participant signs the informed consent form, they will be asked to complete a 10-minute survey (**Attachments 2e and 2f**) prior to the start of the interview or focus group. In-depth interviews are scheduled to last approximately one hour (**Attachments 2c, 7, and 8**), and Focus Groups are scheduled to last approximately 90 minutes (**Attachment 2d, 7, and 8**), and all participants will be informed of this prior to the interview. All sessions will be conducted in person. Interviews and focus groups will be conducted in various locations across the metropolitan Atlanta, Houston, and Miami metropolitan areas. For interviews and focus groups, we will work with each participant to establish a convenient time and location. For focus groups, we will take into account participant availability and preference to decide into which group to schedule a participant.

Contract researchers actively involved in data collection activities will meet the studies training requirements. The contract research team with access to names, contact information, or interview recordings will be required to read and sign a "Rules of Behavior" document, which explains the rules and guidelines for collecting, logging, storing, and destroying personally identifiable information, including names and contact information.

The contact (**Attachment 2b**) and consent forms (**Attachments 3a and 3b**) will be the only forms containing participant names; all other data collection forms will utilize a unique study identification number. The Contact Form will be the only document that links the participant's name to their study identification number. The Contact Form will be maintained only on paper and will never be translated into electronic format. The contract research team will collect contact information on the Contact Form for the purpose of scheduling interviews and focus groups. The signed Informed Consent and Contact Forms will be stored separately in locked cabinets isolated from other study data.

Audio files will be stored on the recorders. The recorders will be secured in locked offices, cabinets, or drawers and briefcases when not in use; transcription will be done by contract research staff by listening to the interview or focus group files on the recording device and transcribing the recordings on stand-alone, password protected computers that are not networked (without Internet access). Transcriptionists will take care to remove any names, contact information, or other information that could identify study participants or anyone they discuss.

Interviews and focus group recordings will be transcribed into an encrypted MS Word document. Transcripts will be stored on and edited from a CDC-approved encrypted USB drive plugged into a standalone, non-networked computer at study offices. Qualitative data analysis files will be stored in a FISMA-compliant dedicated data server or on a CDC-approved encrypted USB

drive plugged into a standalone, non-networked computer at study offices. Any other data that can be kept electronically will also be stored in a secure, FISMA-compliant environment or on a CDC-approved encrypted USB drive plugged into a standalone, non-networked computer at study offices. Backup files will be encrypted and maintained on flash drives securely kept under lock and key. At no point will recordings, contact information, or consent forms be transmitted to CDC or shared with CDC in any way. CDC will only receive de-identified transcripts of the interviews and interviews, and aggregate level quantitative data from the screeners and surveys.

This study meets the requirements necessary for a Certificate of Confidentiality, as mandated by Section 301(d) of the Public Health Service (PHS) Act and as amended by Section 2012 of the 21st Century Cure Act, P.L. 114-255 (42 U.S.C. 241(d).[6]The Certificate of Confidentiality further protects the privacy of participants by limiting the disclosure of identifiable, sensitive information. With this Certificate, the research team cannot be forced, for example by court subpoena, to disclose identifying information from participants for any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

CDC has also completed a Privacy Impact Assessment of the data system used by the contractor team (**Attachment 6**). The contractor team also completes an annual renewal process for their data system, and has a current Authority to Operate approval (**Attachment 6**). Public access to the data will be provided at the completion of the study and after the dissemination of the main outcome findings. The study data sharing and use agreement describes in detail how data access will be provided and provisions for protection of privacy, confidentiality, security, intellectual property, or other rights (**Attachment 5**).

3. Methods to Maximize Response Rates and Deal with No Response

We will use the following procedures to maximize participation and to achieve the desired response rate:

- Recruitment materials will be distributed by and/or posted at the participating recruitment sites
- Recruitment materials indicate the voluntary nature of the study
- Interested parties will be informed of the procedures to protect the confidentiality of the information they provide; for example, the issuance of a Certificate of Confidentiality that prevents the release of data in criminal investigations or court hearings
- A $40 token of appreciation will be provided to those participants who complete the 60-minute interview
- A $60 token of appreciation will be provided to those participants who complete the 90-minute focus group

4. Tests of Procedures or Methods to be Undertaken

The research team includes experts with experience conducting HIV research with health departments, community-based organizations, vulnerable populations, and using qualitative methods, including eligibility screening, in-depth interviews and focus groups. The contract research team will convene their Atlanta Community Advisory Board (CAB) to review the project instruments for cultural sensitivity.

All study instruments (including interview and focus group guides) will be pilot tested prior to implementation with no more than nine volunteers, all of whom will have prior experience working with the MSM community. Pilot testing will ensure the instruments are worded appropriately, flow in a logical manner, and the data solicited is in line with the question's logic as well as study objectives. The intention of the pilot test is to evaluate the instruments, not collect data; therefore, pilot data will not be retained nor included in study data. Study staff will be internally trained on all study procedures prior to piloting, and will subsequently attend an interviewer training on the piloted instrument.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Exhibit 5.1 below lists the study team members consulted on the aspects of research design and those who will be collecting and analyzing the information. Please note: The CDC staff are primarily responsible for providing technical assistance in the design and implementation of the research; assisting in the development of the research protocol and data collection instruments for CDC IRB review; working with investigators to facilitate appropriate research activities; and analyzing data and presenting findings at meetings and in publications. The CDC staff will neither collect data from nor interact with research participants. Members of contract research team will collect all study-related data. No names or contact information will be linkable to information reported to the CDC. All members of the research team will work together to analyze the data and generate reports containing summaries of the findings.

Data collection (in-depth interviews and focus groups) will convene when it is permitted by the local and state authorities. Respondents and staff will be appropriately distanced (at least six feet), and all will be required to wear face masks. We will adhere to the CDC guidelines for prevention of COVID-19 at the time that CDC approves in-person (small group) research activities.

Exhibit 5.1: Study Consultants

Team Member	**Organization**	**Phone**	**Email**
Ayana Stanley	CDC	770-488-3906	ing9@cdc.gov
Damian Denson	CDC	404-639-6125	dvd5@cdc.gov
Patricia Bessler	CDC	404-639-8239	vey4@cdc.gov
Janet McNicholl	CDC	770.488.3928	jkm7@cdc.gov
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Bryan Gale	IMPAQ International	443-259-5186	bgale@impaqint.com
Elizabeth Gall	IMPAQ International	443-259-5216	egall@impaqint.com

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